UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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AMAR SINGH, Individually and On Behalf of All Others Similarly Situated,

Plaintiff,

- against -

HANS G.C.P. SCHIKAN, BERNDT A.E. MODIG, GILES V. CAMPION, COLLEEN A. DEVRIES, LUC M.A. DOCHEZ, REMI DROLLER, DAAN ELLENS, PETER GOODFELLOW, MARTIJN KLEIJWEGT, DAVID MOTT, PATRICK VAN BENEDEN, J.P. MORGAN SECURITIES LLC, CITIGROUP GLOBAL MARKETS INC., LEERINK SWANN LLC (N/K/A LEERINK PARTNERS LLC), WEDBUSH SECURITIES INC., KBC SECURITIES USA INC., TROUT CAPITAL LLC, AND PROSENSA HOLDING N.V.,

Defendants.

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MEMORANDUM AND ORDER

14 Civ. 5450 (NRB)

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

These actions are brought under Sections 11 and 15 of the Securities Exchange Act of 1933 against Prosensa Holding N.V. ("Prosensa"), its underwriters, and certain of its officers and directors (collectively, "defendants"), on behalf of a purported class of investors who purchased or otherwise acquired shares of Prosensa pursuant to the Registration Statement issued in connection with the company's June 2013 initial public offering. Presently before the Court is defendants' motion to dismiss the complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). For the reasons stated herein, this motion is granted.

BACKGROUND

I. Factual Background

A. DMD and Drisaspersen

Duchenne muscular dystrophy ("DMD") is a rare neuromuscular disorder that causes progressive muscle loss, leading to severe disability and premature death. Id. ¶ 48. It is triggered by a genetic mutation that causes the dystrophin gene to produce inadequate amounts of dystrophin, a protein needed to keep muscles intact. Id. DMD primarily affects boys and young men, occurring in about one in 3500 boys worldwide. Id. ¶ 49. The main sign of DMD is worsening muscle weakness, with symptoms generally appearing between one and four years of age. Id. Affected children experience developmental delays and most require full-time wheelchair use by age twelve. Later in the disease's progression, respiratory muscles weaken and cardiac function is impacted, making the disease "universally fatal." The average life expectancy for one diagnosed with DMD is twenty-seven years. Id. ¶¶ 50-51. There are currently no approved DMD disease-modifying therapies. Id. ¶ 51.

Prosensa is a biotechnology company based in Leiden, Netherlands, that "engages in the discovery and development of RNA-modulating therapeutics for the treatment of genetic disorders." Id. ¶¶ 2, 45. In 2003, it entered into an exclusive licensing agreement with the Leiden University Medical Center that

allowed Prosensa use of the Center's "proprietary RNA modulation exon-skipping technology"[1] in developing treatments for DMD. Id. "Drisaspersen," Prosensa's lead product, is intended to treat DMD by skipping exon 51 for the dystrophin gene with the help of this technology. Id. ¶ 55.

In October 2009, Prosensa announced a development partnership with GlaxoSmithKline ("GSK"), under which GSK received exclusive rights to develop and license drisasperson. Id. As part of this collaboration, GSK was responsible for "fund[ing] and conduct[ing] the clinical development and commercialization of drisaspersen," and had "complete control over such activities." Reg. Stmt. at 10. See also id. at 11 ("GSK will fund all our costs and expenses associated with the further clinical development of, and has sole decision-making authority and is responsible for all research, development, regulatory, manufacturing, marketing, advertising, promotional, launch and sales and other commercial activities in connection with drisaspersen . . . . GSK has the right to make decisions regarding the development and commercialization of product candidates under the collaboration without consulting us . . . .").

[1] As the pleadings explain, exons are sections of DNA that code for a protein and are interspersed with introns. In the process of protein production, introns are cut out and discarded to leave only exons. In exon skipping, the cellular machinery is encouraged to "skip over" an exon using "molecular patches" that mask the exon, so it can be essentially ignored during protein production. As a result, if successful, exon skipping may be able to mask DMD symptoms. Id. n.5.

B. The Drisaspersen "DEMAND" Studies

In September 2010, GSK initiated a Phase II study of drisaspersen ("DEMAND-II"), which would be completed in April 2013. Am. Cmplt. ¶¶ 7, 56. The 53-participant, 48-week trial compared two different doses of drisaspersen with a placebo. Reg. Stmt. at 91. The trial's primary endpoint was defined as "the distance walked in the six minute walk test (or '6MWD') between the placebo group and the continuous active-treatment group at a dose of six mg/kg/week after twenty-four weeks."[2] Id.

In December 2010, GSK began a Phase III study ("DEMAND-III"), with results expected to be announced in the fourth quarter of 2013. Id. ¶ 8. The study was a randomized, double-blind, placebo-controlled trial, assessing drisapersen at a dose of six mg/kg/week in 186 boys with a primary endpoint of the 6MWD at forty-eight weeks. Id.

Notably, DEMAND-III had lessened enrollment criteria as compared to DEMAND-II.[3] "For example, the DEMAND-II study only enrolled boys capable of standing up from the floor in seven

[2] "The six minute walk test (6MWT) is a test that measures the distance a subject can walk in 6 minutes using a standardized corridor length and turning point at each end (the six minute walk distance or 6MWD). This test has been used in observational research studies to follow the natural history of DMD disease progression over time as subjects gradually lose the ability to walk." Am. Cmplt. ¶ 60.

[3] As defendants note, "[w]hile Phase II studies are typically 'well controlled, closely monitored, and conducted in a relatively small number of patients,' Phase III studies are expanded significantly and 'usually include from several hundred to several thousand subjects.'" Def's Br. at 5 (quoting 21 C.F.R. § 312.21).

seconds or less, whereas the DEMAND-III study had no maximum time for standing up. The lessening of the enrollment criteria resulted in the subject children being older and having more advanced DMD than those subjects in the DEMAND-II study." Id. ¶ 9. See Reg. Stmt. at 93 ("A total of 53 DMD subjects aged 5 and above with a rise from the floor of less than 7 seconds were recruited [for DEMAND-II]."); id. at 94 ("The [DEMAND-III] study assesses . . . drisaspersen . . . in 186 boys over five years of age and with a minimum 6MWD of 75 meters at enrollment."). DEMAND-III also utilized a wider range of locations and new testing sites. "In fact, the DEMAND-III study was conducted at 44 centers in 19 countries (compared to the DEMAND-II study which was conducted at only 13 centers)." Am. Cmplt. ¶ 11.

In April 2013, following the completion of the DEMAND-II trial, Prosensa and GSK presented abbreviated results from the study. Id. ¶ 57. The companies announced that drisaspersen had conferred a significant difference in walking distance compared to the placebo, specifically reporting a 117-foot difference in the distance walked in six minutes between those treated with drisaspersen versus placebo. Id.

While undertaking these clinical trials, Prosensa faced increasing competition from Sarepta Therapeutic's "eteplirsen," which was also in clinical trials at the time of Prosensa's IPO and was acknowledged in the Registration Statement as its key DMD

competitor. Id. ¶ 64. In particular, on June 19, 2013, nine days before Prosensa's planned initial public offering, Sarepta reported a continued sustained benefit in walking distance through eighty-four weeks of its phase 2b, 12-person study. Id. ¶ 69.

C. The Registration Statement

In anticipation of its initial public offering, Prosensa filed a Registration Statement with the SEC on May 24, 2013, and filed six subsequent amendments, the last of which was filed on June 27, 2013. Id. ¶ 74. The Registration Statement provided investors with background on DMD, tracking "the natural history of the disease" (the progression of a disease process in an individual over time), and explaining the use of the 6MWD in assessing DMD's natural history.[4] Id. ¶¶ 59-61. It also included a graph, which served as a "[c]onceptual representation of 6-minute walking distance performance by DMD patients and healthy controls," illustrating "the typical decline in 6MWD performance by boys with DMD over age 7." Id. ¶ 63; Reg. Stmt. at 89.

With regard to DEMAND-II, it stated that "[a] Phase II placebo-controlled study of drisapersen in 53 DMD patients was

[4] See, e.g., Reg. Stmt. at 88 ("Several key studies have demonstrated the effect of DMD on 6MWD. One study reported an average 57 meter decrease at 52 weeks from baseline in average 6MWD by boys with DMD, whereas comparable healthy boys showed an average increase in 6MWD of 13 meters. A more recent study of 113 boys reported an average decrease in 6MWD of 23 meters in the first year of observation and 65 meters in the second year. In the latter study, when grouped by age, boys below 7 years remained stable with a slight increase in average 6MWD in the first and second years, but the average 6MWD of boys over 7 declined by about 42 meters and 80 meters, respectively.").

completed and demonstrated a statistically significant and clinically important difference in the primary endpoint, which was the distance walked in the six minute walk test, or 6MWD, between the placebo group and the continuous active-treatment group at a dose of 6 mg/kg/week after 24 weeks. This clinically meaningful benefit was maintained after 48 weeks of treatment, and drisapersen was well tolerated throughout the duration of this study." Am. Cmplt. ¶ 58; Reg. Stmt. at 1. Later in the Registration Statement, it provided more details about the design and implementation of the study, explaining that "GSK initiated this exploratory placebo-controlled study of drisaspersen at a 6mg/kg (subcutaneous) dose in September 2010. The study consisted of three arms [further described at length] . . . . A total of 53 DMD subjects aged 5 and above with a rise from the floor of less than 7 seconds were recruited. The primary endpoint was 24-week efficacy." Reg. Stmt. at 93.

With regard to DEMAND-III, the Registration Statement informed investors that "[a] pivotal Phase III study of drisapersen was initiated in December 2010, and results are expected in the fourth quarter of 2013. This study is a randomized, double-blind and placebo-controlled trial, assessing drisapersen at a dose of 6 mg/kg/week in 186 boys. The primary endpoint is the 6MWD at 48 weeks." Am. Cmplt. ¶ 81; Reg. Stmt. at 2. Again, it provided additional information on the study several

pages later, stating that "GSK initiated this ongoing pivotal randomized, double-blind, placebo controlled study in December 2010. The study assesses once-weekly subcutaneous administration of drisaspersen at 6 mg/kg dosing in 186 boys over five years of age and with a minimum 6MWD of 75 meters at enrollment. The goal of the study is demonstrate a mean improvement of 30 meters in 6MWD at 48 weeks compared with placebo. . . . Enrollment is complete. Results are currently expected to be made public in the fourth quarter of 2013." Reg. Stmt. at 94.

The Registration Statement also included information about the sites used in the studies. It noted that "clinical trials are conducted in countries outside the European Union and the United States, which may . . . expose us to risks associated with clinical investigators who are unknown to the EMA or the FDA, and different standards of diagnosis, screening and medical care." Id. at 14. It further specified that "Phase II clinical trials are generally conducted in a limited patient population . . . [while] Phase III clinical trials are undertaken in large patient populations to . . . further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites." Id. at 107. Specifically regarding drisaspersen, it announced that "[t]o date, over 300 patients have participated in clinical studies of drisapersen at more than 50 trial sites in 25 countries . . . ." Id. at 2, 83.

On June 27, 2013, GSK announced that the FDA had verbally notified GSK that drisaspersen had been granted "breakthrough therapy designation" for treatment of DMD. Am. Cmplt. ¶¶ 12, 75. Prosensa subsequently amended its Registration Statement to include information about this designation.

The same day, June 27, 2013, the SEC declared the Registration Statement effective, and Prosensa priced its IPO, which ultimately closed on July 8, 2013. Id. ¶¶ 12-13, 77. It sold more than 6.9 million shares to the public for $13 per share. Id. ¶¶ 14, 78.

D. DEMAND-III Results Announced

On September 20, 2013, Prosensa and GSK issued a press release in which they announced that drisaspersen had not met its primary endpoint in the DEMAND-III study. Id. ¶¶ 16, 89; see also id. ¶ 89 ("[T]here was no treatment difference in key secondary assessments of motor function: 10-meter walk/run test, 4-stair climb and North Star Ambulatory Assessment."). In a subsequent conference call, Prosensa management stated that those receiving the placebo had decreased fifty-three meters on the 6MWD, whereas those receiving the drug had decreased forty-two meters, a minimal difference. In addition, they announced that roughly ten percent of those given placebo and ten percent of those given treatment had lost ambulation altogether. Id. ¶ 90. "When asked by an analyst to explain the different outcomes between the Phase II (DEMAND-II) and the Phase III (DEMAND-III) efficacy outcomes,

Defendant Schikan admitted that the Phase II study included 'a younger patient population with better performance.' [He] explained that the average age in the Phase III testing in the treatment group that received the drug was 8.3 years old versus approximately 7 years old in the Phase II testing," such that the "Phase II study was 'designed to recruit to a younger age . . . .." Id. ¶ 92.

Following this announcement, the share price dropped from a high of $24 per share to close on September 20 at $7.14 per share.[5] Id. ¶ 97. Subsequently, on January 13, 2014, GSK and Prosensa ended their partnership, with Prosensa retaining rights to drisaspersen and programs for the treatment of DMD. Id. ¶ 98. Finally, on November 24, 2014, Prosensa and BioMarin Pharmaceutical Inc. announced that BioMarin would offer to purchase all outstanding Prosensa shares for $17.75 per share, roughly thirty-six percent above the IPO share price. Id. ¶ 100.

II. Procedural Background

Plaintiff Amar Singh filed an initial class action against defendants on July 18, 2014. On September 16, 2014, Patricia Voit filed a motion to serve as lead plaintiff, which we granted on October 9, 2014.

[5] At the time this action was filed on July 18, 2014, Prosensa stock was trading at approximately $9 per share.

On December 29, 2014, plaintiffs filed the Amended Complaint. This complaint alleges that "the Registration Statement contained materially false and/or misleading statements and/or omitted material information . . . concerning the development status of drisapersen, the DEMAND-III study, the prospects for drisapersen's regulatory approval, and the future commercial prospects of drispersen," in violation of Section 11 and Section 15 of the Securities Act. Am. Cmplt. ¶ 15. Specifically, plaintiffs claim that the Registration Statement failed to disclose that: (1) "the enrollment criteria for DEMAND III had been substantially relaxed," (2) "the Company utilized various locations and new testing sites in . . . DEMAND III," (3) "the DEMAND-III clinical study was flawed due to its relaxed enrollment criteria," (4) "due to the significantly different patient populations in the DEMAND-II and DEMAND-III studies, comparisons of the two clinical studies would be rendered unreliable," and (5) "Defendants lacked a reasonable basis for their positive statements concerning . . . drisaspersen." Id.

On February 12, 2015, defendants filed a joint motion to dismiss the Amended Complaint for failure to state a claim under Rule 12(b)(6). The motion was fully briefed on April 15, 2015, and oral argument was held on April 23, 2015.

DISCUSSION

I. Legal Standards

On a motion to dismiss under Rule 12(b)(6), the Court must accept as true all factual allegations in the complaint and draw all reasonable inferences in plaintiff's favor. ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 98 (2d Cir. 2007) ("ATSI"); Grandon v. Merrill Lynch & Co., 147 F.3d 184, 188 (2d Cir. 1998). Nonetheless, "[f]actual allegations must be enough to raise a right of relief above the speculative level, on the assumption that all of the allegations in the complaint are true." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007); see also Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009). Thus, a plaintiff must allege "enough facts to state a claim to relief that is plausible on its face." If a plaintiff "ha[s] not nudged [his] claims across the line from conceivable to plausible, [his] complaint must be dismissed." Id. This pleading standard applies in "all civil actions." Iqbal, 556 U.S. at 684 (internal quotation marks omitted).

To state a claim under Section 11 of the Securities Act, "a plaintiff need show that a registration statement: (1) contained an untrue statement of material fact; (2) omitted to state a material fact required to be stated therein; or (3) omitted to state a material fact necessary to make the statement therein not misleading." Arfa v. Mecox Lane Ltd., 10 Civ. 9053, 2012 WL 697155, at *4 (S.D.N.Y. Mar. 5, 2012) aff'd, 504 F. App'x 14 (2d

Cir. 2012) (internal quotation mark omitted). When pleading an actionable omission, plaintiffs must, "at a minimum, plead facts to demonstrate that allegedly omitted facts both existed, and were known or knowable, at the time of the offering." Scott v. Gen. Motors Co., 12 Civ. 5124 LTS-JLC, 2014 WL 4547837, at *5 (S.D.N.Y. Sept. 15, 2014). In addition, "[t]o fulfill the materiality requirement there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available." Arfa, 2012 WL 697155, at *5 (quoting Basic Inc. v. Levinson, 485 U.S. 224, 231 (1988)).

Finally, Section 15 provides for "control person" liability, and requires that a plaintiff show (1) a primary violation of the Securities Act and (2) "control" by the defendant. See Rombach v. Chang, 355 F.3d 164, 177–78 (2d Cir. 2004).

II. Analysis

A. No Misstatements or Omissions

i. Plaintiffs' Argument

We first note that, as confirmed by plaintiffs' counsel at oral argument, plaintiffs have not alleged that the Registration Statement contained any affirmative misstatements. See Oral Argument Tr. at 2. Rather, plaintiffs' complaint concerns only alleged omissions regarding certain differences between the DEMAND-II and DEMAND-III studies: namely, DEMAND-III's reduced

enrollment criteria and, to a lesser extent, its expanded testing locations. Essentially, plaintiffs argue that defendants knew or should have known at the time the Registration Statement was filed that, as a result of these differences, the DEMAND-III study was fundamentally flawed and was not likely to produce positive results as DEMAND-II had. Accordingly, plaintiffs contend, the Registration Statement should have highlighted these differences and should have disclosed the negative impact these differences would likely have on the study's findings and therefore on the drug's prospects.

Plaintiffs do not dispute, however, that the key details of both studies, including their respective enrollment criteria and DEMAND-III's expanded testing universe, were disclosed in the Registration Statement. See Reg. Stmt. at 93 (Phase II Study involved "53 DMD subjects aged 5 and above with a rise from the floor of less than 7 seconds."); id. at 94 (Phase III study involved "186 boys over five years of age with a minimum 6MWD of 75 meters at enrollment"); id. at 107 ("Phase II clinical trials are generally conducted in a limited patient population . . . . Phase III clinical trials are undertaken in large patient populations . . . in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites."); id. at 2, 83 ("To date, over 300 patients have participated in clinical studies of drisapersen at more than 50 trial sites in 25 countries

. . . ."). Thus, no facts per se were omitted from the prospectus. Cf. In re Progress Energy, Inc., 371 F. Supp. 2d 548, 552 (S.D.N.Y. 2005) ("[I]t is indisputable that there can be no omission where the allegedly omitted facts are disclosed.").

Rather, what plaintiffs allege is lacking in the Registration Statement is essentially an extra level of disclosure spelling out inferences and drawing conclusions for investors. See, e.g., Pl's Opp'n at 19 ("[T]he Registration Statement utterly failed to connect the fact that . . . the older patient population used to enroll the Demand-III study would . . . compromise the results of that study . . . ."") (emphasis added). However, defendants were not required to draw out such inferences or to make such forecasts in order to provide complete and accurate disclosures. Nonetheless, we address each of plaintiffs' specific claims of nondisclosure below, see Am. Cmplt ¶ 15; supra at 11, concluding that no claim is actionable under Section 11.

ii. Alleged Failure to Highlight or Characterize Differences in the Studies (Claims 1 and 2)

Plaintiffs first allege that defendants failed to disclose that "the enrollment criteria for DEMAND III had been substantially relaxed" and that DEMAND-III used many more new testing sites. Again, plaintiffs concede that facts regarding these topics were included in the Registration Statement, but fault defendants for failing to emphasize these particular changes and for failing to note that these changes were likely to negatively impact the study.

However, the studies were described in the Registration Statement in sections helpfully entitled "Ongoing Clinical Development" (sub-headed "Clinical Trials and Drisaspersen") and "Government Regulation - Clinical Trials," with each study or type of study listed chronologically therein. The Statement therefore did not need to highlight these differences as the relevant information--each study's design and results, if available--was easily located and the studies were accurately described seriatim, allowing investors to compare the trials themselves. See, e.g., Arfa v. Mecox Lane Ltd., 10 Civ. 9053, 2012 WL 697155, at *6 (S.D.N.Y. Mar. 5, 2012) aff'd, 504 F. App'x 14 (2d Cir. 2012) (finding no misstatement or omission where registration statement included chart with relevant information, such that "simple comparison" of chart's components would have revealed the fact that was the subject of the claim); In re TVIX Sec. Litig., 12 Civ. 4191 LTS, 2014 WL 2575776 (S.D.N.Y. June 9, 2014) aff'd sub nom. Elite Aviation LLC v. Credit Suisse AG, 588 F. App'x 37 (2d Cir. 2014) (finding no Section 11 claim where plaintiffs "contend that the Offering Documents should have spelled out and quantified particular risks").

Similarly, the fact that information about the studies was set out logically under appropriate headings, alongside related information, demonstrates that it was not impermissibly "buried beneath other information," as plaintiffs assert. Cf., e.g., In

re Flag Telecom Holdings, Ltd. Sec. Litig., 618 F. Supp. 2d 311, 325 (S.D.N.Y. 2009) (finding information impermissibly buried where "defendants rely on . . . scattered disclosures in various amendments, annexes and exhibits to the Prospectus and Registration Statement"); In re Alstom SA, 406 F. Supp. 2d 433, 453 (S.D.N.Y. 2005) (finding information impermissibly buried where it was "separated into two, non-consecutive footnotes" and "the language used . . . makes it virtually impossible to discern what exactly the company is alluding to"); Comas v. Merrill Lynch & Co., 92 Civ. 6560 (KC), 1993 WL 800778, at *4 n.3 (S.D.N.Y. July 2, 1993) (finding disclosure regarding underwriter not buried even in the middle of a lengthy prospectus because it was "logically located in a section entitled "UNDERWRITING").

Nor were defendants' disclosures deficient because they failed to characterize the differences between the studies in a certain way. By contrast, the law is clear that companies need not depict facts in a negative or pejorative light or draw negative inferences to have made adequate disclosures. See, e.g., Klamberg v. Roth, 473 F. Supp. 544, 551 (S.D.N.Y. 1979) ("[S]o long as material facts are disclosed or already known, it is not deceptive to fail to 'characterize' those facts with 'pejorative nouns and adjectives,' or to fail to verbalize all adverse inferences expressly."); Solow v. Citigroup, Inc., 10 Civ. 2927 (RWS), 2012 WL 1813277, at *4 (S.D.N.Y. May 18, 2012) aff'd, 507 F. App'x 81

(2d Cir. 2013) ("[A defendant is] not obligated to characterize its performance or future outlook in negative terms, speculate on future negative results or paint themselves in the most unflattering light possible."); Harrison v. Rubenstein, 02 Civ. 9356 (DAB), 2007 WL 582955, at *13 (S.D.N.Y. Feb. 26, 2007) ("[A company is] under no duty to 'to direct conclusory accusations at itself or to characterize its behavior in a pejorative manner' in its public disclosures."). Rather, having disclosed the factual information on the studies' design, the Registration Statement does not fail simply because it does not use the eye-catching or negative phrasing that plaintiffs would have wished, such as that DEMAND-III "drastically lessened" its enrollment criteria, Am. Cmplt. ¶ 9, or that DEMAND-II was specifically "designed to recruit to a younger age," see Oral Argument Tr. at 7, 9.

iii. Alleged Failure to Disclose that DEMAND-III was Flawed and/or Could Not be Compared to DEMAND-II (Claims 3 and 4)

Plaintiffs' broader claim that defendants should have disclosed that the differences in the DEMAND-III study would cause it to fail, and would render comparisons between it and DEMAND-II unreliable, is equally unavailing. First, plaintiffs do not allege that defendants knew the actual composition of DEMAND-III (i.e., that it was populated by an older set of participants who would fare worse during testing): they do not dispute that GSK, rather than Prosensa, had control over the study and that only GSK, rather

than Prosensa, knew the study's actual composition. As such, plaintiffs have made no allegations suggesting that defendants could have known that the study would in fact produce worse results. Cf. In re ProShares Trust Sec. Litig., 889 F. Supp. 2d 644, 656 (S.D.N.Y. 2012) aff'd, 728 F.3d 96 (2d Cir. 2013) (rejecting claim of misstatement or omission based on plaintiffs' assertion that "defendants knew in advance . . . that large losses would occur" because any knowledge or calculation would "necessarily rely on . . . inputs [that] could not be known in advance").

In the absence of data establishing that DEMAND-III would not meet its endpoints, defendants were not required to predict negative results or to hypothesize its failure.[6] See, e.g., Schoenhaut v. Am. Sensors, Inc., 986 F. Supp. 785, 792 (S.D.N.Y. 1997) (finding no Section 11 claim where "[t]here is no allegation that any defendant actually expected that sales . . . would decline following the offering," and "the Complaint merely alleges that the Prospectus failed to predict that the Company's future prospects were not going to be as bright as its past"); Fisher v. Ross, 93 Civ. 0275 (JGK), 1996 WL 586345, at *7 (S.D.N.Y. Oct. 11, 1996) ("The plaintiff also argues that Ilio was experiencing delays

[6] Indeed, the statement by defendant Schikan on which plaintiffs repeatedly seek to rely--in which he hypothesizes that the different results in DEMAND-II and DEMAND-III may spring from the difference in the ages of the studies' participants, see Am. Cmplt. ¶ 92--was made only after the results of the study were announced, as a conjecture colored by hindsight.

in obtaining letters of credit . . . and that the delays had adversely affected Ilio's financial performance. . . . The undisputed evidence demonstrates, however, that the facts as they existed at the time of Prospectus were disclosed in the Prospectus[and] that the adverse impact of the delayed letters of credit was not recognized until well after the Offering Period . . . . The plaintiff's [Section 11] claim is classic fraud by hindsight and cannot survive."); Shiry v. Moore, 94 Civ. 1485 (SBA), 1995 U.S. Dist. LEXIS 22054, at *28 (N.D. Cal. 1995) ("Plaintiffs claim that SciClone should have predicted that it was likely that . . . the Phase III trial . . . would not show a statistically significant treatment effect. This does not state a claim for securities fraud because Defendants had no duty to predict the outcome of the blinded trial.").

The conclusion that defendants were not required to posit that their study might fail is all the more appropriate where, as here, such speculation would have been based solely on facts disclosed in the Registration Statement, from which investors were equally free to assess the study's likelihood of success. See, e.g., Blackmoss Investments Inc. v. ACA Capital Holdings, Inc., 07 Civ. 10528, 2010 WL 148617, at *8 (S.D.N.Y. Jan. 14, 2010) ("The Complaint alleges that the Prospectus failed to disclose . . . that ACA had substantially increased its exposure to risky CDOs by purchasing below-investment grade bonds in some of its CDO deals

in 2005 and 2006. However, [there is no Section 11 claim because] the Prospectus disclosed that ACA's investments included investments in these low-grade bonds."); In re Ultrafem Inc. Sec. Litig., 91 F. Supp. 2d 678, 699 (S.D.N.Y. 2000) ("The defendants were not under an obligation to disclose that [the menstrual cup product's] 'prospects for mass acceptance posed an extreme risk' . . . [because] the problems with other menstrual cup devices were disclosed . . . [and they] provided accurate hard data from which analysts and investors can draw their own conclusions . . . .") (internal quotation marks omitted); Shiry, 1995 U.S. Dist. LEXIS 22054, at *29 ("Plaintiffs also assert that a [negative] spontaneous remission rate in the Phase II trial indicated that there would be a similar result in the Phase III trial. . . . [However,] the Prospectus disclosed the spontaneous remission rate in the Phase II trial, and thus Plaintiffs had sufficient facts to form their present conclusions when they read the Prospectus.").[7]

iv. Non-Actionable Critique of Study Design

Ultimately, plaintiffs' complaint more closely resembles a criticism of the DEMAND studies' design than a claim for

[7] Cf. also Sable v. Southmark/Envicon Capital Corp., 819 F. Supp. 324, 334 (S.D.N.Y. 1993) ("A reasonable investor will not be deceived by nondisclosure of inferences if he or she can draw whatever inferences might be appropriate based on disclosed facts."); Gulf & W. Indus., Inc. v. Great Atl. & Pac. Tea Co., 476 F.2d 687, 697 (2d Cir. 1973) ("[T]he disclosure requirements of the securities laws require 'nothing more than the disclosure of basic facts so that outsiders may draw upon their own evaluative experience in reaching their own investment decisions with knowledge equal to that of the insiders.'").

nondisclosure, a form of hindsight pleading not cognizable under Section 11. See Abely v. Aeterna Zentaris Inc., 12 Civ. 4711 PKC, 2013 WL 2399869, at *8 (S.D.N.Y. May 29, 2013) (rejecting the claim that "defendants misrepresented or omitted material information about the design and findings of the Phase 2 study" because "plaintiff's allegations amount to a non-actionable critique of defendants' study design"); cf. Davison v. Ventrus Biosciences, Inc., 13 Civ. 3119 (RMB), 2014 WL 1805242, at *7 (S.D.N.Y. May 5, 2014) reconsideration denied, 13 Civ. 3119 (RMB), 2014 WL 4460346 (S.D.N.Y. July 2, 2014) (no false statements under Section 10(b) where plaintiffs argued that "representations regarding the results of the . . . Phase II studies . . . were misleading because 'Defendants failed to disclose the inclusiveness and unreliability of the results generated from the German Study due to the small sample size,'" as plaintiffs "do not allege that Defendants' Class Period statements misrepresented any facts regarding the German Study, including its size or any other facts about its methodology, but, instead, [essentially] criticize the study's methodology as unreliable"); In re TVIX Sec. Litig., 2014 WL 2575776, at *4 ("'[P]laintiffs are not allowed to plead Section 11 claims with the benefit of 20/20 hindsight' because 'Section 11 claim[s] cannot be based on a backward-looking assessment of the registration statement.'").

As noted in the Registration Statement, Phase III studies are necessarily more expansive than Phase II studies and therefore necessarily involve more risk. The fact that DEMAND-III ultimately failed where DEMAND-II succeeded does not mean that defendants knowingly designed a flawed study and then failed to disclose those design flaws, as plaintiffs would seem to suggest; by contrast, it indicates that the Phase III study served its intended purpose of identifying whether the drug would provide meaningful benefit across a wider population. Likewise, the fact that elements of DEMAND-III's design may have led the drug to fall short of the trial's primary endpoints does not indicate that defendants knew that or why the drug would fail, let alone that they committed securities fraud. Rather, defendants disclosed the facts known at the time of the IPO that would subsequently affect the study and the stock price, and were not required to foresee the failure of the study or the specific reasons for its hypothetical failure. As such, defendants fulfilled their disclosure obligations and plaintiffs' claims are dismissed.[8]

B. No Unwarranted Positive Statements (Claim 5)

Defendants also challenge the Amended Complaint insofar as it is based on allegations that the Registration Statement "lacked a

[8] Defendants also argue that plaintiffs' Section 11 claims should be dismissed because, even if "there was some additional piece of information about study design . . . that should have been included, any additional information would not have been material." Def's Br. at 21. Because we find that the Registration Statement did not include misstatements or omissions, we do not reach this argument.

reasonable basis for [its] positive statements concerning the development status of drisapersen, the DEMAND-III study, the prospects for drisapersen's regulatory approval, and drisapersen's future commercial prospects." Am. Cmplt. ¶ 88.

First, defendants argue that plaintiffs have failed to identify any positive statements allegedly made by defendants and have therefore failed to state a claim. See, e.g., Blackmoss Investments Inc. v. ACA Capital Holdings, Inc., 07 Civ. 10528, 2010 WL 148617, at *7 (S.D.N.Y. Jan. 14, 2010) ("For liability to attach under either Section 11 or 12(a)(2) of the Securities Act . . . a plaintiff must identify the statement that it deems to be false or misleading.") (citing Lasker v. N.Y. State Elec. & Gas Corp., 85 F.3d 55, 57–58 (2d Cir. 1996)); In re WorldCom, Inc. Sec. Litig., 303 F. Supp. 2d 385, 390 (S.D.N.Y. 2004) ("Although the pleading requirements for a Section 11 claim are minimal, Section 11 does require that a plaintiff identify an 'untrue statement of a material fact' or allege that the registration statement 'omitted to state a material fact.'"). Second, in the event that a positive statement could be identified, defendants claim that such a statement would nevertheless be protected under the bespeaks caution doctrine as a result of risk disclosures included in the Registration Statement.[9]

[9] Under the bespeaks caution doctrine, "[a] forward-looking statement accompanied by sufficient cautionary language is not actionable because no reasonable investor could have found the statement materially misleading."

Plaintiffs counter that "the false and misleading statements alleged here concern historical or present fact," rather than forward-looking statements, and they assert that the risk disclosures identified by defendants in the Registration Statement are not sufficiently directed to the omitted risks to "bespeak caution." See Pl's Opp'n at 23. However, plaintiffs do not respond to defendants' claim that no particular positive statements have been identified--and, indeed, do not at any point identify a specific "positive statement" that they believe was misleading. Instead, they simply reiterate that defendants failed to disclose that the study was compromised and would fail to reach its endpoints. As such, any claim regarding unwarranted positive statements fails and is dismissed.

C. Section 15 Liability

Finally, because defendants have failed to state a claim under Section 11, their "control person liability claim pursuant to section 15 of the Securities Act . . . must also fail for want of a primary violation." ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co., 553 F.3d 187, 207 (2d Cir. 2009); see also, e.g., Garber v. Legg Mason, Inc., 537 F. Supp. 2d 597,

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Iowa Pub. Employees' Ret. Sys. v. MF Global, Ltd., 620 F.3d 137, 141 (2d Cir. 2010). This doctrine is strictly limited to forward-looking statements, and the cautionary language concerning those statements "must be specific, prominent and must directly address the risk that plaintiffs claim was not disclosed. The requirement that the cautionary language match the specific risk is particularly important, considering that most, if not all security offerings contain cautionary language." In re Flag Telecom Holdings, Ltd. Sec. Litig., 618 F. Supp. 2d 311, 322 (S.D.N.Y. 2009).

618 (S.D.N.Y. 2008) aff'd, 347 F. App'x 665 (2d Cir. 2009) ("As there are no surviving primary violations upon which plaintiffs could rest these claims, plaintiffs' Section 15 . . . claims are dismissed."). Plaintiffs' Section 15 claims are therefore dismissed.

CONCLUSION

For the aforementioned reasons, defendants' motion to dismiss is granted.[10] This Memorandum and Order resolves docket no. 29 and the Clerk of Court is respectfully requested to close this case.

SO ORDERED.

Dated: New York, New York
May 4, 2015

NAOMI REICE BUCHWALD
UNITED STATES DISTRICT JUDGE

[10] We deny plaintiffs' cursory request for leave to amend, made in one sentence "on the final page of their brief in opposition to defendants' motion to dismiss, in boilerplate language and without any explanation[, either in writing or at oral argument,] as to why leave to amend was warranted." Food Holdings Ltd. v. Bank of Am. Corp., 423 F. App'x 73, 76 (2d Cir. 2011); see also Malin v. XL Capital, Ltd., 312 F. App'x 400, 402-03 (2d Cir. 2009).